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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	C.A. No. 21-1015 (GBW)
)	
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	REDACTED - PUBLIC VERSION
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**REPLY LETTER TO THE HONORABLE GREGORY B. WILLIAMS
FROM SAREPTA THERAPEUTICS, INC. REGARDING SAREPTA'S
MOTION FOR LEAVE TO AMEND ITS ANSWER AND COUNTERCLAIMS**

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July 31, 2023

Dear Judge Williams:

In support of Sarepta Therapeutics, Inc. (“Sarepta”)’s motion for leave to amend its Answer and Counterclaims (D.I. 272), Sarepta respectfully replies to the letter from Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”), dated July 26, 2023 (D.I. 281).

I. Sarepta’s Motion Is Not Untimely Under Rule 16(b)

Because of the high burden in proving inequitable conduct, courts encourage challengers to raise inequitable conduct *after* “the challenger *confirm[s]* its suspicions and *gather[s]* the evidence necessary to sustain its claim.” *Lipocine Inc. v. Clarus Therapeutics, Inc.*, 2020 WL 4794576, at *3 (D. Del. Aug. 18, 2020). That is what Sarepta did. As discovery progressed, Sarepta became aware of evidence suggesting that NS misled the USPTO to secure allowance of its patents, and that [REDACTED]. But Sarepta needed to obtain testimonial and documentary evidence to confirm these suspicions. After months of negotiation, NS finally produced select, responsive documents on **June 21, 2023** revealing that

[REDACTED]
[REDACTED] **June 26-27, 2023**, Sarepta confirmed its suspicions:

[REDACTED] Ex. 1 (D.I. 272), ¶¶177-78, 184-86, 190-203, 207.

NS’s focus on documents available earlier in discovery (D.I. 281 at 1-2) ignores the need for the discovery Sarepta obtained later. NS’s statement that Sarepta relied on only one document produced on June 21, 2023 is wrong, as NS *reproduced* [REDACTED] that day, *unredacting* previously-redacted data that serves as key support for Sarepta’s claim. Ex. 3. Thus, Sarepta “needed the deposition[] of the inventor[] and was justified in taking certain discovery” in order to confirm [REDACTED]

[REDACTED] *Roquette Frères v. SPI Pharma, Inc.*, 2009 WL 1444835, at *6 (D. Del. May 21, 2009).

After obtaining information critical to its inequitable conduct allegation, Sarepta promptly approached NS just **two weeks later** and proposed amendments containing **over 130 new paragraphs** citing this new evidence **over 65 times**. The cases NS relies on are therefore inapposite because the movant there waited *months* after obtaining key information before seeking leave to amend. *See, e.g., Sonos, Inc. v. D&M Holdings Inc.*, 2017 WL 476279, at *2 (D. Del. Feb. 3, 2017) (allegations rested *entirely* on information available *months to years* before the deadline for amendments); *Carrier Corp. v. Goodman Glob., Inc.*, 49 F. Supp. 3d 430, 433 (D. Del. 2014) (similar). Good cause exists for Sarepta’s motion, which rests on a “new set of facts obtained and confirmed during discovery which took place after the Scheduling Order’s deadline for amended pleadings.” *See ICU Med., Inc. v. RyMed Techs., Inc.*, 674 F. Supp. 2d 574, 578 (D. Del. 2009).

II. Sarepta’s Inequitable Conduct Claim Is Not Futile

A. Mr. Watanabe’s Withheld Data

During prosecution of the ’361 patent, NS repeatedly alleged that the claimed oligonucleotides exhibited superior skipping activity over the prior art. [REDACTED]. *See, e.g., Ex. 1, ¶¶134-38, 201, 207, 214-17.* NS avers that the allowance was not “solely based on (‘but-for’)” [REDACTED] because the USPTO Notice of Allowance did not indicate “reli[ance] on” them and NS’s claim amendments during prosecution could instead have led to allowance. D.I. 281 at 3-4.

NS is wrong. NS cites no case indicating that but-for materiality requires express articulation in the Notice of Allowance. Rather, withheld information is “but-for material if the

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PTO would not have allowed a claim had it been aware of” it. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (en banc). Here, NS repeatedly [REDACTED] to overcome a prior art rejection, *including in the response immediately preceding allowance*. Ex. 1, ¶¶134-39. Had the Examiner known of [REDACTED], they would not have allowed the ’361 patent. *Id.*, ¶¶217, 226. Further, NS is wrong in alleging that allowance was “primarily” based on its final claim amendments. D.I. 281 at 3-4. While NS argues that its amended claims no longer covered an antisense oligonucleotide falling “squarely within” the scope of the prior art (*id.*), the Examiner had described *both sequences*, including the one remaining after amendment, as “fall[ing] squarely within” the “superior target region” disclosed in the prior art. Ex. 1, ¶135. Thus, the amendments did *not* free the allowed claims of the prior art and the record supports Sarepta’s assertion that the Examiner relied on the alleged unexpected results. NS’s misrepresentations and the contrary withheld data were but-for material.

B. The Sazani Paper

NS’s arguments regarding the Sazani paper lack merit. NS first argues that Sarepta’s amended pleading fails to plausibly allege that Sazani was not cumulative of other cited prior art. D.I. 281 at 4-5; Ex. 1, ¶228. To the contrary, Sarepta pled that Sazani “provides *non-cumulative, material* information” not disclosed in the prior art of record. Ex. 1, ¶228. NS further alleges that Sazani is not materially different from two publications of record, the ’591 and ’212 publications. D.I. 281 at 4-5. But NS must stitch together disparate disclosures to arrive at the *complete* chemical structure of AVI-4658 reported in Sazani. *Id.* (citing ¶[0046], ¶[0299], Fig. 1A of the ’591 publication). NS also points to the single mention of the word “safety” in the ’212 publication as allegedly cumulative to the extensive safety studies that Sazani conducted in nonhuman primates. *Id.* (citing ¶[0030] of the ’212 publication). NS’s arguments confirm that Sazani is *not* cumulative.

NS also alleges that Sarepta fails to “explain how genotoxicity is . . . relevant” to NS’s patent claims. *Id.* But, as Sarepta’s amendments explained, NS’s claims are directed to PMOs for use in treating DMD patients. Ex. 1, ¶227. [REDACTED]

[REDACTED] *Id.*, ¶228. NS also asserts that Sarepta’s pleading failed to allege that [REDACTED] had specific intent to deceive. D.I. 281 at 4-5. But Sarepta pled that [REDACTED]. See, e.g., Ex. 1, ¶¶190-203. The “single most reasonable inference” is that [REDACTED] specifically intended to deceive the USPTO. *Id.*, ¶230. Sarepta’s allegations lead to a “plausible inference” of specific intent, thus satisfying the requirement under Rule 9(b). *Baxalta Inc. v Bayer Healthcare L.L.C.*, 2021 WL 7441631, at *7 (D. Del. Apr. 22, 2021).

C. The ’361 Patent and NS’s Other Patents-in-Suit

Inequitable conduct in one patent can “render unenforceable all claims which eventually issue from the same or a related application,” especially when the conduct is “related to” the later-issued claims. *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 417 F. Supp. 2d 580, 595 (D. Del. 2006). The NS Patents claim the *same* priority, share the *same* specification, *and most significantly claim the same subject matter*—PMOs targeting positions 36 to 60. Ex. 1, ¶¶98-122, 218. [REDACTED] during prosecution of the ’361 patent are therefore equally material to the later-issued patents, which would not have issued but for the *same* misconduct. Ex. 1, ¶¶98-121, 126-40, 218; *eSpeed*, 417 F. Supp. 2d at 595. NS’s other patents are unenforceable because each bears an “immediate and necessary relation” to the ’361 patent and benefitted from the earlier inequitable conduct. See *Guardant Health, Inc. v. Found. Med., Inc.*, 2020 WL 2477522, at *6-9 (D. Del. Jan. 7, 2020) (a showing that “the patents-in-suit are closely related in substance” justified a finding of infectious unenforceability).

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac
Attachment

cc: Clerk of the Court (via hand delivery; w/attachment)
All Counsel of Record (via electronic mail; w/attachment)

EXHIBIT 3

From: [Doi, Elsa](#)
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Subject: Nippon Shinyaku, Ltd. v. Sarepta Therapeutics, Inc., No. 1:21-cv-01015-LPS – Document Production
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Attachments expire on Jul 21, 2023



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